K003500

MAY 3 0 2001

510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990

REBSTOCK IMPLANT STEEL ANEURYSM CLIPS

and

REBSTOCK TITANIUM ANEURYSM CLIPS

September 1st, 2000

Submitted by:

REBSTOCK Instrumente GmbH
In Breiten 12
78589 Dürbheim / Germany
Tel.: +49 7424-6734
Fax: +49 7424-4334

1. Device Discription

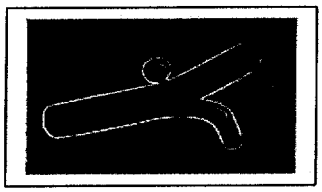
Product:	Rebstock Aneurysm Clip
Common Name:	Aneurysm Clip
Clssification Name:	CLIP, ANEURYSM
Medical Speciality:	Neurology
Product Code:	HCH
Device Class:	2
Tier:	2
Regulation Number:	882.5200

The REBSTOCK ANEURYSM CLIPS mentioned above will be available as temporary or permanent devices, made from Implant Steel or Titaium.
The Clips may be applied by two different clip appliers:
1) For Aneurysm Clip composed of implant steel → Clip appliers with implant steel jaws
2) For Aneurysm Clip composed of Titanium alloy → Clip appliers with Titanium alloy jaws.

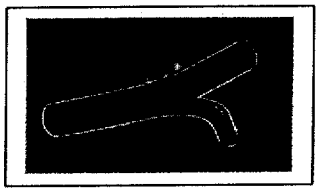
2. Intended use

Rebstock Instrumente GmbH's permanent and temporary Aneurysm Clips are intended for either the permanent and temporary occlusion of blood vessels, e.g., cerebral aneurysms. To avoid damage to the clips, they should only be used with the Rebstock Instrumente GmbH Aneurysm Clip Applier.

Illustrations



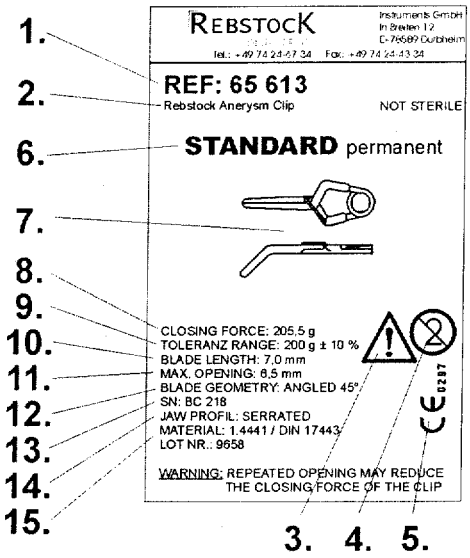
Aneurysm



Cliped and deflated aneurysm

3. Technological Characteristics, packaging label, instruction manual

REBSTOCK ANEURYSM CLIPS do not contain any new technological risks or characteristics when compared to other legally marketed devices because they are manufactured according to the prevailing standards.
The technological characteristics of each clip are listed on the of packaging label.



Description
1. Reference Number
2. Type Specification "Rebstock Aneurysm Clip"
3. Direction "Pay Attention to using instruction"
4. Direction "For single use only"
5. "CE"-sign with short cut "0297" of the notified body „German Registrar for Management"
6. Indication „STANDARD" or „MINI" and „permanent" and "temporary"
7. Illustration of the clip
8. Tolerance range of the closing force
9. Blade length
10. Maximum opening
11. Blade geometry
12. Serial number which is marked on the clip by laser technology
13. Jaw profile
14. Material Code (Stainless Steel = 1.4441/DIN 17443; Titanium = 3.7165/ISO 5832-3)
15. Lot number of the material

4. Used Material: Composition and Biocompatibility

REBSTOCK ANEURYSM CLIPS are manufactured from two types of material.

1. High quality alloy implant steel

The used high quality alloy implant steel is manufactured by a German steel manufacturer in conformity with the DIN 17443, ISO 5832-1 and ASTM-F138 (special steel grade 316 L). It´s components secure the high grade characteristics:

- highest stability
- minimum magnetism
- highest rust and acid resistance.

2. Titanium alloy

The used Titanium alloy Ti6Al4V is in conformity with the

- **ASTM-F136:**
  Specification for wrought Titaniumium 6Al-4V Eli alloy for surgical Implant Applications
- **ISO 5832/3:**
  Implant for surgery metallic materials – Part 3: Wrought Titaniumium 6-Aluminium 4-Vanadium Alloy

K003500

5. Compatibility to other systems

The REBSTOCK ANEURYSM CLIP system is not compatible to other traded systems.
For a correct and secure handling they have to be applied with the REBSTOCK clip appliers.

6. Substantial Equivalence

The REBSTOCK ANEURYSM CLIP system share similar function, application, styles of jaw and dimensions to

- SUGITA TITANIUM ANEURYSM CLIP **(#K990202)**
- AESCULAP YASARGIL TITANIUM ANEURYSM CLIPS **(#K983758)**
- PACIFIC SURGICAL INNOVATIONS TAKA ANEURYSM CLIP **(#K972750)**
- AESCULAP YASARGIL ANEURYSM CLIPS **(#K970050)**
- ELECTRA INSTRUMENTS SPETZLER Ti 100 ANEURYSM CLIPS **(#K955064)**
- SUGITA ANEURYSM CLIPS **(#K782040)**

7. Certified quality system

REBSTOCK Instruments GmbH has a certified quality system acc. to normative standard DIN **EN ISO 9001, DIN EN 46001** and **MDD 93/42/EEC II** from June, 14TH 1993.
The quality management system and the product where certified by the German notified body "German Registrar for Management – DQS".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

Mr. Dieter Rebstock
Managing Director
Rebstock - Instruments GmbH
In Breiten 12
D-78589 Dürbheim,
Germany

Re: K003500
Trade/Device Name: Rebstock Aneurysm Clips
Regulation Number: 882.5200
Regulatory Class: II
Product Code: HCH
Dated: May 3, 2001
Received: May 9, 2001

Dear Mr. Rebstock:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003500

IFU-Statement

510(k) Number: K003500

Device Name: Rebstock Aneurysm Clips

Indication For Use:

Rebstock Instrumente GmbH's permanent and temporary Aneurysm Clips are intended for either the permanent and temporary occlusion of blood vessels, e.g., cerebral aneurysms. To avoid damage to the clips, they should only be used with the Rebstock Instrumente GmbH Aneurysm Clip Applier.

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003500